

Brodnick et al.

S/N: 09/661,064

REMARKS

Claims 1-15 are pending in the present application. Claims 16-35 have previously been withdrawn. Claim 36 is newly presented herein. In the Office Action mailed July 17, 2003, the Examiner rejected claims 1, 2, and 11-13 under 35 U.S.C. §102(b) as being clearly anticipated by Murphy (WO 98/40009). Next, the Examiner rejected claims 1, 2, 4-6, and 11-13 under 35 U.S.C. §103(a) as being unpatentable over Bornn (USP 5,564,429). Claims 1 and 2 were rejected under 35 U.S.C. §103(a) as being unpatentable over David et al. (USP 5,544,649). Claims 3 and 7-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn (or David et al. or Murphy). Claims 14 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn (or David et al. or Murphy) in view of Morgan et al. (5,782,878).

The Examiner rejected claims 1, 2, and 11-13 by stating that the claims are "clearly anticipated" by Murphy. The Examiner, however, provided no basis or explanation of the §102(b) rejections.

To anticipate a claim, the reference must teach each and every element of the claim. See MPEP § 2131. Therefore, to establish a proper rejection under §102(b) the Examiner must show exactly how the reference teaches each and every element of the claim. That is, simply asserting that a claim is "clearly anticipated" does not provide the requisite support required to sustain a rejection under §102(b). Specifically, as illustrated by Examiner's Note 7.15 from MPEP §706.02(i), a statement such as "clearly anticipated" or "anticipated" must be accompanied by "an explanation at the end of the paragraph." MPEP §706.02(i). As such, Applicant hereby requests reasoned statements demonstrating the Examiner's interpretation of the claims and an explanation as to how the claims are "clearly anticipated" by the reference.

is necessary

While Applicant is not obligated to respond to unsubstantiated rejections, Applicant has chosen to highlight some of the clear distinctions in order to eliminate further confusion and expedite the prosecution of the current application. Applicant believes one of ordinary skill in the art will readily acknowledge numerous distinctions between the current invention and the art cited by the Examiner.

Regarding claim 1, Applicant has amended the claim to clarify that the wireless communications interface is "capable of transmitting patient ECG data and video to a remote health care provider." That is, claim 1 is specific that the wireless interface is capable of transmitting video from the patient to a remotely located health care provider. However, Murphy only teaches transmission of still pictures "grabbed" from a video camera. Murphy p.

Brodnick et al.

S/N: 09/661,064

3, Ins. 21-24, p. 8, Ins 7-13, and p. 14, Ins. 19-27. While Murphy teaches the use of a video camera for providing "moving images of the patient on the head up display and LCD display," it is clear that only still images "grabbed" from the video are transmitted "to the medical expert at the remote location." Murphy p. 8, Ins. 8-12. Therefore, unlike the claimed invention, Murphy teaches a wireless communications interface that is only capable of transmitting intermittent still pictures of the patient. On the other hand, claim 1 is clear that the wireless communications interface can transmit video. One of ordinary skill in the art will readily recognize the numerous differences between a communications interface capable of transmitting video and an interface only capable of transmitting still pictures. As such, claim 1 is clearly patentably distinct from Murphy.

Regarding claims 2 and 11-13, Applicant does not believe Murphy teaches that which is claimed. However, since the Examiner has failed to provide any basis for the rejection beyond stating that the claims are "clearly anticipated," Applicant cannot address the Examiner's basis of rejection. Again, as required under the CFR and MPEP, Applicant requests reasoned statements demonstrating the Examiner's interpretation of the claims and an explanation as to how the claims are "clearly anticipated" by the reference, so that Applicant may address any misinterpretations or misapplications of the art by the Examiner. Nevertheless, Applicant believes claims 2 and 11-13 are in condition for allowance pursuant to the chain of dependency.

The Examiner then rejected claims 1, 2, 4-6, and 11-13 under §103(a) as being unpatentable over Bornn et al. However, the Examiner's rejection does not address each and every element of the claims nor does the Examiner's rejection provide any citations to support the Examiner's conclusions. The Examiner is reminded that in order to establish a *prima facie* case, the Examiner must not only show that the combination includes each and every element of the claimed invention, but also provide "a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Simply, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

Regarding claim 1, the claim explicitly states that the ECG monitor is "on-demand". However, the Examiner failed to address this element when rejecting claim 1. Bornn et al.

Brodnick et al.

S/N: 09/661,064

clearly teaches that the patient must wear "a torso band and an optional shoulder band" at all times. Col. 4, Ins. 5-6. That is, if the patient moves beyond the communications range of the system or removes the torso band, the monitor will enter an alert condition. Col. 3, Ins. 15-52 and Col. 4, Ins. 3-25. The patient must then reenter the communications range and/or replace the torso band within a predetermined time interval in order to avoid sending an emergency notification. Col. 3, Ins 15-25. Simply, the ECG monitor taught in Bornn is not on-demand because a patient does not have the option to use the ECG monitor at his or her discretion. Simply, the patient is required to continuously wear the torso band and stay within the bounds of operating conditions. Therefore, Bornn et al. clearly teaches a continuous and mandatory ECG monitor, not an on-demand monitor, as claimed. Accordingly, the prior art reference does not teach or suggest all the claim limitations.

If power
is not available
it's not
on demand

Additionally, the Examiner acknowledged that Bornn et al. does not disclose the use of a 12-lead configuration or processing of 12-lead ECG data but asserts modifying Bornn et al. to include such would have been obvious. However, "[a] prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention." MPEP §2144.05. Bornn et al. teaches away from the reception of data from the patient in a standard 12-lead configuration and the production of standard 12-lead ECG data by teaching the use of "pairs of electrodes" in various configurations. Col. 9, Ins. 10-30 and Col. 10, Ins. 1-6. One skilled in the art will immediately recognize that use of "pairs of electrodes" is indicative of bi-polar electrodes, which teaches away from a 12-lead ECG configuration because the 12-lead ECG configuration requires uni-polar electrodes. Thus, Bornn et al. teaches away from a 12-lead configuration by teaching a system that is not capable of a standard 12-lead ECG data acquisition.

The Examiner states that "Murphy is one teaching of many that shows the use of a portable monitor using 12 lead wire assemblies and processing and provides a teach for the 35 USC 103 rejections." However, the Examiner has failed to provide some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings or shown that would be a reasonable expectation of success in combining the teachings. Rather, the Examiner made the conclusionary statement that such systems "provide a complete and easily readable ECG data record for determining cardiac conditions and for allowing more accurate diagnosis of patient conditions." The Examiner failed to support the assertion or show that there would be a reasonable expectation of success in modifying Bornn et al.

Furthermore, Bornn et al. teaches "a torso band and an optional shoulder band." Col. 4, Ins. 5-6 and Figs. 1A and 2A. One of ordinary skill in the art will immediately recognize

Brodnick et al.

S/N: 09/661,064

that the electrode placement consistent with the bands disclosed in Bornn is incapable of producing standard 12-lead ECG data as claimed. Therefore, contrary to the Examiner's assertion, it would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECG monitoring system of Bornn et al. to incorporate a 12-lead wire assembly because such an assembly is entirely inconsistent with the torso and shoulder bands required by Bornn et al. Accordingly, there is no suggestion or motivation to modify the reference to include a 12-lead wire assembly to acquire 12-lead data because Bornn et al. explicitly teaches a different lead assembly incompatible with a 12-lead wire assembly. Also, there would not be a reasonable expectation of success to augment the system of Bornn et al. to include a 12-lead wire assembly because the torso band and optional shoulder band are incompatible with such an assembly and would, therefore, require extensive modifications not supported by the teachings of the art of record. As such, Applicant believes the Examiner has failed to meet the burden required to establish a case of *prima facie* obviousness and further believes claim 1 to be readily distinguishable from Bornn et al. Accordingly, claims 2, 4-6 and 11-13 are also allowable over Bornn et al. pursuant to the chain of dependency.

The Examiner then rejected claims 1 and 2 under §103(a) as being unpatentable over David et al. Again, the Examiner's rejection does not address each and every element of the claims nor does the Examiner's rejection provide any citations to support the Examiner's conclusions. Rather, the Examiner concludes that it would have been obvious to modify the ECG monitoring system of David to include a 12-lead wire assembly simply because such assemblies were known in the art. Applicant is not claiming to have invented the 12-lead wire assembly and the Examiner is reminded that merely stating that such an assembly existed at the time of invention does not meet the burden required under MPEP §2143 to establish a *prima facie* case of obviousness. However, beyond the Examiner's failure to meet the burden require under MPEP §2143, there are numerous distinctions between the claimed invention and the system of David et al.

Regarding claim 1, the claim, in part, calls for "a portable, on-demand ECG monitor." However, the system disclosed in David et al. is incapable of portability. That is, David et al. teaches a system utilizing cable television. One of ordinary skill in the art will readily recognize that the equipment required for cable television is too cumbersome to support portability. Furthermore, David et al. teaches that such equipment be integrated with a chair, which makes portability movement impractical. As such, David et al. teaches directly away from "a portable, on-demand ECG monitor."

Brodnick et al.

S/N: 09/661,064

Nevertheless, to further clarify claim 1, Applicant has amended the claim to call for the wireless communication interface to be integrated with the ECG monitor. David et al. is clear that the wireless communications interface is not integrated with the ECG monitor. Specifically, referring to Fig. 6 of David et al., the communications interface is shown removed from the ECG monitor. Therefore, claim 1 is further distinguishable over David et al. As such, Applicant believes claim 2 is distinguishable over David et al. pursuant to the chain of dependency.

The Examiner continues to make blanket rejections of entire groups of claims as unpatentable over any one of Bornn et al., David et al., or Murphy. The Examiner rejects claims 3, 7-10, 14 and 15 without specifically addressing each and every element of each and every claim. Furthermore, when substantiating the rejection, the Examiner merely states that "Bornn (or David or Murphy) discloses" but fails to provide any support for the Examiner's interpretation of each reference or show how the Examiner's interpretation applies to each and every element of each and every claim. Again, MPEP §2143 requires a three prong showing to establish a *prima facie* case of obviousness. The Examiner has failed to substantiate the Examiner's position with support from the cited references and, accordingly, has failed to meet any of the three prongs required under MPEP §2143.

For Example, when rejecting claims 14 and 15, the Examiner states that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the monitoring system taught by Bornn (or David or Murphy), with a GPS system connected to the communications interface as taught by Morgan, since such a modification would provide an monitoring system with a GPS system connected to the communications interface to allow for the remote determination of the location of the patient by the health care provider." The Examiner's statement is obviously a conclusionary statement based on hindsight of the claimed invention and does not (1) show some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) establish a reasonable expectation of success, or (3) show that the prior art references teach or suggest all the claim limitations. MPEP §2143. As such, the Examiner has clearly not met the burden required to establish a case of *prima facie* obviousness under MPEP §2143. Therefore, claims 3, 7-10, 14 and 15 are not only in condition for allowance pursuant to the chain of dependency but Applicant believes the claims are distinguishable over the art of record.

Applicant also requests entry and consideration of claim 36 newly presented herein to further define the present invention. Claim 36 calls for the wireless communication

Brodnick et al.

S/N: 09/661,064

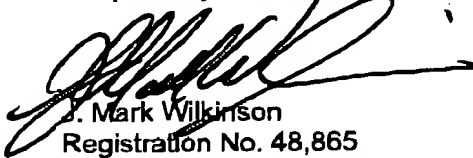
interface as being capable of concurrently transmitting patient ECG data and voice data to a health care provider in a wireless transmission. It is believed that claim 36 further defines the present invention over the art of record. Specifically, the references fail to teach a 12 lead wire assembly and a portable ECG device wherein the ECG device includes an on-demand and portable ECG monitor and a communications interface to wirelessly transmit ECG and voice data to a health care provider in a wireless transmission. For example, Murphy clearly teaches the transmission of data over one channel and transmission of voice over another channel. See Murphy, p. 11, ll. 10-13.

Therefore, in light of the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1-15 and 36.

Additionally, because of the Examiner's unsubstantiated §102 rejection as discussed above, Applicant requests a non-final action on the merits to afford Applicant an opportunity to address the Examiner's basis of rejection.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,



J. Mark Wilkinson
Registration No. 48,865
Direct Dial 262.376.5016
jmw@zpspatents.com

Dated: October 3, 2003
Attorney Docket No.: GEMS8081.040

P.O. ADDRESS:
Ziolkowski Patent Solutions Group, LLC
14135 North Cedarburg Road
Mequon, WI 53097-1416
262-376-5170